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ASX Announcement

Starpharma announces positive final DEP® irinotecan Phase 2 clinical trial results

DEP® clinical results to be presented at the ASCO 2024 Annual Meeting

Key Points

- *Positive, clinically significant results from Starpharma's Phase 2 clinical trial of DEP® irinotecan, reported in full for the first time here, will be presented as an oral presentation at the 2024 ASCO Annual Meeting.*
- *The DEP® irinotecan Phase 2 trial met its objectives, with endpoints demonstrating positive anti-tumour efficacy in multiple cancers and confirming the product's favourable safety and tolerability profile.*
- *Key efficacy results in heavily pre-treated patients with **advanced colorectal cancer,** 98% of whom experienced cancer progression following prior irinotecan treatment, include:*
    - *DEP® irinotecan in combination with 5-fluorouracil (5-FU) and leucovorin (LV) achieved **median progression-free survival (mPFS) of 4.2 months**, which is approximately 68% longer than published data on mPFS for conventional irinotecan plus 5-FU/LV as second-line therapy.*
    - *In these patients, the **disease control rate (DCR) was 86%,** and the **objective response rate (ORR) was 14%**, which also compares favourably to the published ORR of 4% for conventional irinotecan plus 5-FU/LV.*
- *Key efficacy results in heavily pre-treated patients with **advanced platinum-resistant/refractory ovarian cancer** include:*
    - *DEP® irinotecan monotherapy once every 2 weeks achieved a **median progression-free survival (mPFS) of 9.3 months**, which is approximately 3 times longer than published data on standard-of-care (SoC) single-agent therapies, including paclitaxel.*
    - *In these patients, the **disease control rate (DCR) was 100%,** and the **objective response rate (ORR) was 43%**, which also compares very favourably to published ORRs of ~6 to 12% for SoC single-agent therapies.*
- *DEP® irinotecan administered as a monotherapy or in combination with 5-FU/LV was confirmed to be very well-tolerated, with a notable lack of severe gastrointestinal adverse events and no instances of cholinergic syndrome, in contrast to standard irinotecan.*
- *Several patients who have had prolonged responses to therapy and are experiencing ongoing clinical benefit continue to receive access to DEP® irinotecan treatment and will be monitored for safety and any change to their disease.*
- *Full clinical data from Starpharma's Phase 2 trial of DEP® cabazitaxel, reported in October 2023, will also be presented at ASCO in a separate oral presentation.*

Melbourne, Australia; 27 May 2024: Starpharma (ASX: SPL, OTCQX: SPHRY), dedicated to helping patients with significant illnesses, such as cancer, achieve improved health outcomes through the

application of our unique dendrimer technology, today announces the full results of the Phase 2 open-label clinical trial of DEP® irinotecan. The trial met its objectives, with endpoints demonstrating positive anti-tumour efficacy of DEP® irinotecan in heavily pre-treated patients with a range of difficult-to-treat, advanced, metastatic cancers, including colorectal cancer (CRC) and platinum-resistant ovarian cancer.

DEP® irinotecan is a novel, patented nanoparticle formulation of SN38[1], the active metabolite of the widely used anti-cancer drug, irinotecan (marketed as Camptosar®). Developed using Starpharma's proprietary DEP® dendrimer technology, DEP® irinotecan was designed to solubilise and directly deliver SN38 to cancer tissue, eliminating the need for liver metabolism and thereby avoiding the production of toxic metabolites.

Key commercial opportunities exist for DEP® irinotecan in colorectal and ovarian cancer indications. These opportunities are highlighted by the favourable efficacy results for DEP® irinotecan for both indications compared with published data on standard-of-care (SoC) treatment options, and the safety data consistently demonstrating an improved safety profile compared with standard irinotecan for these patients with advanced disease.

Both these cancers remain significant unmet medical needs. Colorectal cancer is the third most common cancer in the US, with survival rates that vary significantly based on the stage of cancer, a person's age and general health. For advanced disease, where cancer has spread to other parts of the body (metastasised), the 5-year relative survival rate is only 17%[2]. Platinum-based chemotherapy is the backbone of treatment for ovarian cancer, but most women will relapse and develop drug resistance to these agents. Platinum-resistant ovarian cancer has a poor prognosis, and the few treatment options available have only shown marginal benefit[3].

In this context, the results for DEP® irinotecan showing clinically meaningful improvements in efficacy, measured by progression-free survival and objective responses, and tolerability when compared to standard irinotecan and other SoC treatment options are particularly impressive and demonstrate the promising clinical utility and high value potential of DEP® irinotecan in patients with advanced colorectal and platinum-resistant ovarian cancer.

DEP® irinotecan clinical efficacy results (Phase 1/2 combined data)

The 114 patients enrolled in the study (Phase 1 N=7, Phase 2 N=107) ranged in age from 31 to 78 years and had exhausted all standard-of-care treatment options prior to commencing therapy with DEP® irinotecan.

Key efficacy results in heavily pre-treated patients with **advanced colorectal cancer[4] (CRC)**, 98% (54/55) of whom experienced cancer progression following up to 4 lines of prior irinotecan treatment, include:

- **Median progression-free survival (mPFS)** was 4.2 months when DEP® irinotecan was administered once every 2 weeks (Q2W) in combination with 5-FU/LV in patients who had received a median of 3 prior anticancer regimens (N=17);
- In patients evaluable[5] for assessment of tumour size changes (N=14), the **disease control rate (DCR)**[6] was 86%, and the **objective response rate (ORR)**[7] was 14%, with **stable**

[1] SN38 is of the class of drugs known as topoisomerase-1 inhibitors, which includes other drugs such as topotecan and deruxtecan, which is the active moiety of the approved anticancer antibody-drug conjugate (ADC), trastuzumab-deruxtecan (T-DXd, Enhertu®).
[2] https://www.cancer.net/cancer-types/colorectal-cancer/statistics
[3] https://www.cancerresearch.org/cancer-types/ovarian-cancer
[4] Colorectal cancer (CRC), or bowel cancer, is cancer affecting the large intestine and the rectum.
[5] All efficacy response data reported in this announcement are for evaluable patients. Evaluable patients are those that received ≥1 dose cycle of DEP® irinotecan and had a CT scan to assess response to treatment at ≥~8 weeks after commencement of treatment with DEP® irinotecan.

disease (SD) and **partial responses (PRs)** lasting up to 45 weeks. Several patients continue to receive the DEP® irinotecan 5-FU/LV combination therapy.

These outcomes for DEP® irinotecan plus 5-FU/LV represent an approximate 68% improvement in mPFS and 3.5 times greater ORR compared with published data in advanced CRC patients for conventional irinotecan plus 5-FU/LV ("FOLFIRI") as second-line therapy (*i.e.,* in patients even less heavily pre-treated than in the current study), which report a mPFS of 2.5 months and an ORR of 4%[8].

- When DEP® irinotecan was administered as a monotherapy Q2W/Q3W in patients who had received a median of 4 prior anticancer regimens, **median progression-free survival (mPFS)** was 2.1 months (N=38) and **disease control rate (DCR)** in evaluable patients (N=31) was 48%, with disease control lasting up to 72 weeks.

Key efficacy results in heavily pre-treated patients with **advanced platinum-resistant/refractory ovarian cancer** include:

- **Median progression-free survival (mPFS)** was 9.3 months when DEP® irinotecan was administered as a monotherapy Q2W in patients who had received a median of 6 prior anticancer regimens and 30 prior treatment cycles (N=8);

- In monotherapy Q2W evaluable patients (N=7), the **disease control rate (DCR)** was 100% and the **objective response rate (ORR)** was 43%, with **stable disease (SD)** and **partial responses (PRs)** lasting up to 62 weeks to date. There are 2 patients continuing to receive DEP® irinotecan therapy due to ongoing responses and significant clinical benefit;

- One patient with no measurable target lesions achieved a **complete response (CR)** evidenced by complete resolution of tumour ascites and pleural effusion;

- Another patient who had a **partial response (PR)** had complete resolution of their target tumour (100% reduction in size) and tumour ascites, and an ovarian cancer tumour biomarker (CA-125[9]) reduction of 98%, with stable non-target tumour lesions;

- More than 75% of patients had ovarian cancer tumour biomarker (CA-125) reductions.

These outcomes for DEP® irinotecan in patients with platinum-resistant ovarian cancer demonstrate up to an approximate 3 times longer mPFS and 3.5 to 7 times greater ORR compared with standard-of-care single-agent therapies for platinum-resistant ovarian cancer, including paclitaxel (Taxol®), topotecan (Hycamtin®), gemcitabine (Gemzar®) or pegylated liposomal doxorubicin (Caelyx®), which report mPFS ranging from 3.1 to 3.6 months and ORRs ranging from ~6 to 12%[10,11].

The mPFS of 9.3 months for DEP® irinotecan monotherapy Q2W is also approximately 50% longer than the mPFS of 6.3 months reported for the combination of standard chemotherapy with the targeted monoclonal antibody, bevacizumab (Avastin®)[11], in patients with platinum-resistant ovarian cancer. The ORR of 43% achieved with DEP® irinotecan monotherapy is also more than 50% higher than the ORR of 27.3% for the chemotherapy plus bevacizumab combination regimen.

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[6] DCR comprises stable disease (SD), partial responses (PR) and complete responses (CR).
[7] ORR comprises PR and CR.
[8] Tournigand et al., FOLFIRI Followed by FOLFOX6 or the Reverse Sequence in Advanced Colorectal Cancer: A Randomized GERCOR Study, *Clinical Oncology*, 2023;41(19):3469-3477. https://doi.org/10.1200/jco.22.02774
[9] CA-125: cancer antigen 125.
[10] Mutch et al., Randomized Phase III Trial of Gemcitabine Compared with Pegylated Liposomal Doxorubicin in Patients with Platinum-resistant Ovarian Cancer, *J Clin Oncol*, 2007;25(19):2811-2818. https://doi.org/10.1200/jco.2006.09.6735
[11] Pujade-Lauraine et al., Bevacizumab Combined with Chemotherapy for Platinum-Resistant Recurrent Ovarian Cancer: The AURELIA Open-Label Randomized Phase III Trial, *J Clin Oncol*, 2014;32(13):1302-1308. https://doi.org/10.1200/jco.2013.51.4489

- When DEP® irinotecan was administered as a monotherapy (Q2W/Q3W combined), **mPFS** was 3.2 months (N=23).

These very promising results in patients with platinum-resistant/refractory ovarian cancer were achieved despite standard irinotecan not being approved for use in this indication. The emergence of resistance to platinum-based therapies in patients with recurrent ovarian cancer is inevitable, and outcomes for these patients remain poor, with limited treatment options available, highlighting a substantial unmet need for new treatments and a promising new market opportunity for DEP® irinotecan.

Promising anticancer activity was also observed in patients with various other cancer types, including breast and pancreatic. A patient with advanced metastatic breast cancer, who had received 12 prior lines of therapy and 119 prior cycles of treatment, received 25 cycles of DEP® irinotecan (Q3W) and achieved stable disease for 72 weeks.

At the time of database lock (DBL), an insufficient number of overall survival (OS) events (i.e., patient deaths) had been reported to allow calculation of median OS endpoints (i.e., survival remained above 50% at DBL).

DEP® irinotecan safety and tolerability

DEP® irinotecan was very well tolerated in this trial, with an improved safety profile, including significantly fewer severe gastrointestinal treatment-related adverse events (TRAEs), compared to published data on conventional irinotecan.

Importantly, there were no reports of severe or life-threatening (≥ grade 3) diarrhoea in colorectal cancer patients and only one report of grade 3 diarrhea in a patient with ovarian cancer following DEP® irinotecan therapy. Similarly, severe nausea was reported in only 2 patients (1.8%), and severe vomiting was reported in only 1 patient (0.9%). This notable lack of gastrointestinal toxicity was despite more than 775 doses of DEP® irinotecan having been administered in this study involving 114 patients. This result is a significant improvement in the side effect profile when compared to conventional irinotecan (Camptosar®) treatment, which is associated with severe or life-threatening diarrhoea in more than 20% of patients[12]. Irinotecan-induced diarrhoea, which is the subject of an FDA "Black Box" warning for standard irinotecan, is frequently associated with the discontinuation of treatment and hospitalisation and can have potentially fatal outcomes.

With DEP® irinotecan, there were also no reports of cholinergic syndrome, which occurs in approximately 47% of patients treated with conventional irinotecan[12]. This problematic adverse event involves symptoms such as acute diarrhoea, slow heartbeat, low blood pressure, increased salivation and tears, blurred vision, excessive sweating, flushing, and abdominal cramping.

Overall, symptomatic TRAEs for DEP® irinotecan were mostly mild to moderate in severity and included nausea, vomiting, fatigue, constipation, decreased appetite and hair loss. Bone marrow toxicity (myelosuppression) was generally uncomplicated and manageable, with colony-stimulating growth factor (G-CSF) used as necessary.

DEP® irinotecan's highly favourable safety and tolerability profile was a key component of the clinical benefit evidenced by patients in this early phase trial. Irrespective of dosing frequency (Q3W or Q2W) and whether monotherapy or the 5-FU/LV combination therapy, many patients were able to receive long-term treatment. For example, long-term treatment was achieved in heavily pretreated, advanced colorectal, ovarian, and breast cancer patients as well as a pancreatic cancer patient, all

[12] Camptosar® (irinotecan) Injection label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020571s048lbl.pdf

of whom received at least 6 months of therapy, with many of these receiving more than 1 year of DEP® irinotecan treatment, including several who have continued access to DEP® irinotecan treatment.

Importantly, there were no immune-mediated adverse events with DEP® irinotecan, making it suitable for combination with immune-oncology agents. The excellent tolerability of DEP® irinotecan makes it a suitable candidate for other combination regimens where the gastrointestinal adverse event profile of standard irinotecan may be problematic. No new adverse events were observed with DEP® irinotecan compared to conventional irinotecan, indicating a lack of toxicity due to the dendrimer scaffold.

DEP® clinical results to be presented in oral presentations at ASCO 2024 Annual Meeting

These final clinical data from the DEP® irinotecan Phase 1/2 trial will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting to be held from 31 May to 4 June 2024 in Chicago. In addition, the positive DEP® cabazitaxel Phase 2 trial results, announced in October 2023, will also be presented in full at the ASCO Meeting. These two oral presentations will showcase the significant advantages of the DEP® dendrimer technology in delivering different classes of cytotoxic chemotherapeutics to achieve improved treatment outcomes for patients with a range of cancers.

DEP® irinotecan and DEP® cabazitaxel have the potential to provide efficacious alternative options for eligible patients with a significantly enhanced safety profile, which could be especially important for patients who may otherwise not be suitable for treatment with the standard chemotherapy option. Both products are supported by a strong international intellectual property portfolio, and Starpharma is looking to license global rights to DEP® irinotecan and DEP® cabazitaxel to a partner with the expertise to maximise their clinical and commercial potential.

The DEP® irinotecan data will be presented at the ASCO Meeting by **Dr Jia (Jenny) Liu MD PhD FRACP**, Medical Oncologist and Principal Investigator at the Kinghorn Cancer Centre, St Vincent's Hospital in Sydney, who commented on the positive Phase 1/2 clinical trial results:

> *"The full DEP® irinotecan / DEP® SN38 trial results are very exciting. DEP® irinotecan in heavily pre-treated, advanced cancer patients demonstrated highly encouraging efficacy results in a range of tumour types. These responses include significant and sustained tumour shrinkage and disease control in patients with irinotecan-pre-treated colorectal cancer and platinum-resistant ovarian cancer.*
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> *"Furthermore, DEP® irinotecan exhibits excellent tolerability, with a distinct lack of severe gastrointestinal toxicity that is a common and problematic feature of standard irinotecan treatment. Such treatment tolerability, combined with sustained disease control, has meant that many of our patients, including those who are quite young with advanced colorectal cancer, have been able to receive long-term treatment and continue to work and engage socially with their peers, which is very important for their quality of life.*
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> *"I'm impressed by the DEP® delivery platform, which is highly flexible and has the potential to more effectively deliver a broad range of compounds, including other cytotoxic and small molecules, as well as radioisotopes, and as a potential alternative to antibody-drug conjugates (ADCs) to treat and image cancers, while avoiding or reducing possible adverse effects.*
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> *"The ASCO annual meeting is the world's biggest global clinical cancer conference. It's noteworthy that these exciting DEP® irinotecan trial results were chosen for an oral presentation, and we are delighted to showcase this very promising and flexible DEP® delivery platform to this important audience."*

Prof. James Spicer MBBS FRCP PhD, professor of experimental cancer medicine at King's College London, and consultant in medical oncology and Principal Investigator at Guy's and St Thomas' NHS Foundation Trust in London, will present the DEP® cabazitaxel data on behalf of Starpharma and the study team at ASCO, and commented on the DEP® cabazitaxel:

"I'm delighted to present the exciting findings for the DEP® cabazitaxel Phase 2 clinical trial at the prestigious ASCO 2024 Annual Meeting in Chicago. Being selected for an oral presentation from thousands of submitted abstracts provides an excellent opportunity to present the full findings from this particular trial and showcase the DEP® delivery platform technology.

"The Phase 2 DEP® cabazitaxel results demonstrated very promising anti-cancer activity in advanced, hard-to-treat cancers, including patients with prostate, esophago-gastric and platinum-resistant ovarian tumours, and showed clinically meaningful responses in patients whose cancer has progressed following prior treatment with taxane therapies.

"Furthermore, DEP® cabazitaxel was well-tolerated in these advanced cancer patients. Notably, little bone marrow toxicity (myelosuppression) was observed even in the absence of preventative G-CSF treatment. This was despite patients being at risk of such chemotherapy-induced toxicity, particularly the relatively elderly prostate cancer patients with extensive bone metastatic disease.

"Given the exciting results, further clinical development of DEP® cabazitaxel is warranted, not only for the treatment of advanced prostate cancer but also platinum-resistant ovarian or esophago-gastric cancers, where there remains a significant unmet need."

Starpharma's Chief Executive Officer, Cheryl Maley, commented:

"Building on the interim data reported by Starpharma in Q1FY24, the final results reported today show very positive efficacy outcomes for DEP® irinotecan in both colorectal and ovarian cancer indications. The results compare very favourably with published data on standard-of-care treatments, indicating the potential for improved quality of life for patients with advanced cancers.

"The patients involved in Starpharma's DEP® irinotecan Phase 2 study were heavily pre-treated, with the colorectal cancer cohort having had a median of 3 lines of prior anti-cancer treatment before entering our study, and the platinum-resistant ovarian cohort having had a median of 6 lines of previous treatment. Almost all the colorectal cancer patients had already progressed following prior treatment with standard irinotecan. This level of pre-treatment and advanced disease makes the efficacy outcomes for DEP® irinotecan even more impressive, especially when the results are compared with standard approved therapies.

"We are excited to present the positive clinical data from Starpharma's Phase 2 trials of both DEP® irinotecan and DEP® cabazitaxel at the 2024 ASCO Annual Meeting. The data demonstrate clinically meaningful anti-tumour efficacy and a favourable safety/tolerability profile for both products in multiple hard-to-treat cancers.

"The ASCO Meeting is the world's most comprehensive gathering of oncology clinicians, researchers and pharmaceutical companies to hear the latest breakthroughs and advancements in cancer treatment. Only a small proportion of submitted abstracts are accepted for presentation at the ASCO Annual Meeting, and this year, fewer than 4% of these accepted abstracts have been designated for full or rapid oral presentation.

"It is, therefore, a significant achievement that both DEP® irinotecan and DEP® cabazitaxel abstracts have been accepted for oral presentation, and underscores the quality and potential clinical impact of the findings in a broad context. The presentations provide Starpharma with the

opportunity to showcase these two products and the DEP® platform technology more broadly to a global audience.

"Promisingly, DEP® irinotecan demonstrated positive outcomes in combination with 5-fluorouracil (5-FU) and leucovorin (LV) for colorectal cancer and as a monotherapy for platinum-resistant ovarian cancer, with significantly longer progression-free survival and disease control rates compared to standard treatments. The safety profile of DEP® irinotecan was favourable, with a notable lack of severe gastrointestinal adverse events and cholinergic syndrome compared to standard irinotecan.

"We are confident that DEP® irinotecan, as monotherapy and in an array of potential combination regimens, presents significant commercial opportunities in colorectal and ovarian cancer indications, potentially addressing unmet medical needs in these challenging-to-treat cancers. Starpharma is seeking a partner to further develop this product for patients in need."

Starpharma would like to thank the patients who participated in the DEP® irinotecan trial, and their families and caregivers, as well as the study investigators and study team who worked on the trial.

ASCO 2024 Annual Meeting Presentation Session Details

DEP® cabazitaxel
Title: Efficacy and safety of dendrimer-enhanced (DEP) cabazitaxel (DEP CTX) in patients with advanced solid cancers in a phase 1/2 trial (P1/2)
Session Title: Oral Abstract Session – Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
Date and Time: Saturday, June 1, 2024; 3:00 PM-6:00 PM CDT
Abstract Number: 3004
https://meetings.asco.org/2024-asco-annual-meeting/15825

DEP® irinotecan
Title: Dendrimer-enhanced (DEP) SN38 (DEP irinotecan) in patients (pts) with advanced solid tumors: A phase 1/2 trial
Session Title: Rapid Oral Abstract – Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
Date and Time: Monday, June 3, 2024; 8:00 AM-9:30 AM CDT
Abstract Number: 3014
https://meetings.asco.org/2024-asco-annual-meeting/15826

About Starpharma

Starpharma (ASX: SPL, OTCQX: SPHRY) is dedicated to helping patients with significant illnesses, such as cancer, achieve improved health outcomes and quality of life through the application of our unique dendrimer technology.

Dendrimers are precise, synthetically manufactured, nanoscale molecules. Their unique properties—including their size, structure, high degree of branching, polyvalency, and water solubility—are advantageous in medical and pharmaceutical applications.

Starpharma uses its dendrimer technology to develop novel therapeutics and to enhance the performance of existing pharmaceuticals. The Company's portfolio includes multiple clinical-stage oncology products, which utilise its Dendrimer Enhanced Product ('DEP®') drug delivery technology, as well as marketed products, including VIRALEZE™ and VivaGel® BV, which utilise SPL7013, a proprietary dendrimer with antimicrobial properties. Starpharma's DEP® drug delivery platform is being used to enhance the effectiveness of existing and novel therapies and to reduce drug-related toxicities through controlled and specified drug delivery.

For more information about Starpharma, visit www.starpharma.com or connect with Starpharma on LinkedIn.

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Disclosure
This ASX Announcement was authorised for release by Chair, Mr Rob Thomas.

Forward-Looking Statements

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other authorities' requirements regarding any one or more product candidates, nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated, or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise. Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document, nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.